



(12)

EUROPEAN PATENT APPLICATION

(43) Date of publication:
23.06.2004 Bulletin 2004/26

(51) Int Cl.7: A61M 1/06, A61B 5/00

(21) Application number: 03405885.9

(22) Date of filing: 11.12.2003

(84) Designated Contracting States:
AT BE BG CH CY CZ DE DK EE ES FI FR GB GR
HU IE IT LI LU MC NL PT RO SE SI SK TR
Designated Extension States:
AL LT LV MK

(30) Priority: 20.12.2002 CH 21882002
27.03.2003 US 401138
17.07.2003 US 621490

(71) Applicant: Medela Holding AG
6340 Baar (CH)

(72) Inventors:
• Kent, Jacqueline Coral
Nedlands, WA 6009 (AU)

- Mitoulas, Leon Robert
Osborne Park, WA 6017 (AU)
- Ramsay, Donna Tracy
Forrestfield, WA 6058 (AU)
- Hartmann, Peter Edwin
Gooseberry Hill, WA 6076 (AU)
- Cregan, Mark Derek
Doubleview, WA 6018 (AU)
- Sadler, Rosalind Jane
Gainsville, FL 32601-4352 (US)

(74) Representative: Clerc, Natalia et al
Isler & Pedrazzini AG
Postfach 6940
8023 Zürich (CH)

(54) Use of a breast pump

(57) A system for detecting a milk surge in a mother's breast has a breast pump (1) with a breast shield (10) for expressing milk from the breast, a collecting container (2), for receiving the milk expressed, and a unit (3, 4) by means of which a quantity of milk received in the collecting container (2) is determined as a function

of time. This system makes it possible to detect the point in time and also the intensity of the milk surge. Application areas are research, in order to gain new knowledge about the breast-feeding behavior of babies and mothers, hospitals and child welfare clinics, in order to resolve breast-feeding problems, and development departments, for the purpose of optimizing breast pumps.

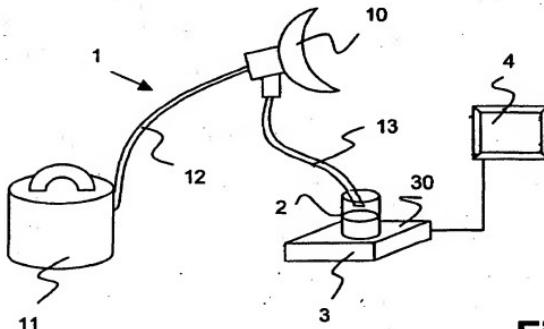


Fig. 1

Description**Technical field**

[0001] The Invention relates to a system and to a process for detecting a milk surge in a mother's breast and to the use of a breast pump for detecting a milk surge.

Prior Art

[0002] The human breast has mammary glands which form balloon-like structures, so-called alveoli. The alveoli are connected to one another via milk ducts which lead to the nipple. The alveoli are enclosed by myoepithelial cells which contract under the influence of oxytocin. A sphincter at the end of the nipple, however, prevents the breast milk from flowing out.

[0003] If a baby then begins to suck at the breast, this is detected by mechanoreceptors in the breast and a corresponding signal is transmitting to the mother's brain. Influenced by emotions, experiences and other external influences, the signal passes to the hypothalamus which thus releases oxytocin.

[0004] The contraction of the myoepithelial cells triggered as a result leads to the alveoli deflating, as a result of which the milk ducts are widened. If the nipple sphincter is then opened by pressure, heat or other external factors, the milk can flow out. This contraction is referred to as the milk surge.

[0005] The prior art discloses breast pumps which are likewise able to express milk from the mother's breast. In particular WO 01/47577 discloses a milk pump which imitates the sucking rhythm of a baby and thus allows milk to be expressed from the breast in as natural a manner as possible.

[0006] Breast-feeding a baby, however, is not always straightforward. The causes of problems may stem from the baby or the mother or from both. It is often difficult, however, to determine the causes precisely. Expressing milk by means of a breast pump can also be problematic for some mothers. For the manufacturers of breast pumps, it is thus important to understand breast-feeding as precisely as possible and to utilize this knowledge in the design of breast pumps. It has been found that essential information for analyzing breast-feeding problems and for optimizing breast pumps may be derived from the mother's milk surge.

[0007] It is another aspect of breast-feeding, that the volume of milk consumed by a baby is determined in order to make sure, that the baby is well fed. The simplest, however also a not very efficient way to do so is to weigh the baby before and after the feeding session.

[0008] US 5'827'191 therefore discloses a method for monitoring a volume of milk during breast feeding, the method utilizing an elastic nipple shaped cover applied over a nipple area of a woman's breast. The cover has holes positioned above the nipple area for passage of milk to the baby's mouth. A micro measurement volume

sensor is located in a space between the nipple and the elastic cover holes to measure the volume of milk flowing therethrough.

[0009] WO 01/54488 also discloses an apparatus for determining the amount of human milk supplied to a feeding baby during a breast-feeding session. A flowmeter is used to measure the milk supply.

Description of the Invention

[0010] It is an object of the invention to provide a system and a process which allows a milk surge to be detected in a straightforward manner.

[0011] This object is achieved by a system and a process having the features of patent claims 1 and 10, respectively.

[0012] It is another object of the invention to provide a system and a process which allows taking samples for milk analysis and/or individual use without interfering with a determination of the milk quantity.

[0013] This object is achieved by a system and a process having the features of patent claims 7 and 14, respectively.

[0014] In the process according to the invention, the milk is expressed into at least one collecting container and the quantity of milk expressed is determined as a function of time. If a milk surge takes place, then the quantity of milk detected increases abruptly. It is thus easy to detect the milk surge.

[0015] The quantity of milk is preferably weighed. However, other determining methods, for example volume measurements, are also possible.

[0016] The change in the quantity of milk over time is preferably directly determined or calculated. This allows the point in time and also the intensity of the milk surge to be detected to better effect.

[0017] The measurement results and measurement curves obtained in this way can be evaluated, and it is possible to draw conclusions about the behavior of the corresponding test individual in response to various external and internal influences. Application areas for the system and process according to the invention are, for example, research, in order to obtain knowledge about the breast-feeding behavior of babies and mothers.

[0018] They may also be used, however, in hospitals or for advising mothers, in order to resolve breast-feeding or expressing problems. The results may also be used in product development, for the purpose of optimizing breast pumps.

[0019] In a variant of the process, the milk is collected in several containers, wherein the quantity of milk expressed is still determined as a function of time. If the quantity of milk is determined by weighing, the containers are preferably placed on the same balance. This enables splitting of milk collection whilst not interfering with the continuous collection of weight data. Since the milk collection is split, the milk samples can be individually analyzed and/or used.

[0019] Further advantageous variants and embodiments can be gathered from the dependent patent claims.

Brief description of the drawing

[0020] The subject matter of the invention is explained hereinbelow with reference to preferred exemplary embodiments illustrated in the attached drawing, in which:

Figure 1 shows a schematic illustration of the system according to the invention;

Figure 2 shows a measurement curve obtained by means of the process according to the invention and a calculated first derivative of the measurement curve;

Figure 3 shows a schematic illustration of the system according to a second embodiment of the invention and

Figure 4 shows a schematic illustration of the system according to a third embodiment of the invention.

Methods of Implementing the Invention

[0021] The system of the invention according to Figure 1 has a breast pump 1, with at least one breast shield 10 for expressing the milk from a human breast, at least one collecting container 2, for receiving the milk expressed, and a unit with a measuring means 3 and an evaluating means 4, by means of which a quantity of milk received in the collecting container 2 is determined as a function of time.

[0022] The measuring means 3 serves for determining the weight or the change in weight of the breast milk located in the collecting container 2. In this preferred exemplary embodiment, this measuring means 3 is a balance, preferably an electromechanical balance with a bearing surface 30, on which the collecting container 2 is arranged.

[0023] The balance 3 is electronically connected to the evaluating means 4, which is preferably a computing system, in particular a computer. In order to transmit the measured values from the balance 3 to the computer 4. It is also possible, however, for the computer 4 and balance 3 to be integrated in a single machine. The measured values may be transmitted at defined time intervals or in a continuous manner.

[0024] In the evaluating means 4, the measured values and/or the change therein are illustrated as a function of time. Figure 2 illustrates a corresponding measurement curve M and the derivative A thereof as a function of time. The y-axis shows the time in minutes, and the x-axis shows the mass in grams. The ovals O in figure 2 indicate the point in time of a milk surge. As can

be seen, the flow of milk increases during a milk surge; the measurement curve M rises more rapidly. In the derivative A, the milk surges appear in the form of peaks and are thus even easier to make out. It can also be seen from the two curves M, A that the milk surge need not always have the same intensity. These curves can be evaluated and the results used for a variety of different purposes mentioned above.

[0025] Figure 1 illustrates a table-top model of a breast pump. This means that the pumping unit is arranged in a housing 11 and is connected, by means of a negative-pressure tube 12, to the breast shield 10. In order for the negative pressure which is necessary for the flow of milk to be achieved therein. The breast shield 10 is connected to the collecting container 2 via a connecting tube 13, with the result that the breast milk can pass through this tube 13 into the container 2, for example a glass or a bottle. This apparatus has the advantage that the mother can move about during the test without falsifying the measurement result.

[0026] It is also possible, however, to use a breast pump in which the collecting container 2 is arranged on the breast shield 10. Here the important factor is for it to be possible to detect the behavior of the flow of milk over time.

[0027] Figure 3 shows a second embodiment of the invention. Instead of one single collecting container 2, several containers 2', 2'', 2''' are used. The containers 2', 2'', 2''' can have the same or different volumes. The number of containers 2', 2'', 2''' depends on the kind of analysis to be made. The three containers shown in figure 3 are therefore only an example. Preferably the containers 2', 2'', 2''' are all connected to the same measuring means 3, which can be any of the measuring means mentioned above. In the example shown in figure 3, the measuring means 3 is again a balance, so that the containers 2', 2'', 2''' are placed on this balance 3.

[0028] The connecting tube 13 is preferably coupled with first moving means 14 for moving the tube 13 from a first to a second of said containers 2', 2'', 2'''. The tube 13 is moved to the next container 2', 2'', 2''' after a predetermined event. It is preferably moved automatically, the means being preferably controlled by the evaluating means 4. It is also possible to connect the evaluation means and the moving means to a separate, but common control means. This event is preferably a time period passed, so that the connecting tube 13 is moved after a set time point. The time point can always be the same or it can change depending on the container to be filled. The event can also be a predetermined quantity of milk collected in one of the containers 2', 2'', 2''' or it can be something else.

[0029] The milk collected in the several containers 2', 2'', 2''' can be analyzed and also used individually. For example, as milk is removed from the breast the fat content of the milk increases and this system allows to track that increase.

[0030] This technique is extremely beneficial for

mothers of premature infants for whom the energy density of milk is very important. The fat is responsible for approximately 50% of the energy in milk therefore, collecting the milk in fractions will provide volumes of milk with different energy densities. These can then be used individually or certain fractions can even be mixed to provide milk of specific energy density - an energy density best suited to the infant's needs.

[0031] Figure 4 shows third embodiment of the inventive system. Here, the measuring means 3, i.e. in this case the balance, is moved by second moving means 15 in order to fill the different containers 2', 2'', 2'''. This moving means 15, which can for example be a motor-driven moving table, where the balance is being placed on, is preferably connected to the evaluation and control means 4.

List of designations

[0032]

- 1 Breast pump
 - 10 Breast shield
 - 11 Housing
 - 12 Negative-pressure tube
 - 13 Connecting tube
 - 14 moving means
 - 15 second means

 - 2 Collecting container
 - 2' Collecting container
 - 2'' Collecting container
 - 2''' Collecting container

 - 3 Measuring means
 - 30 Bearing surface

 - 4 Evaluating means

 - M Measurement curve
 - A Derivative
 - O Oval

Claims

1. A system for detecting a milk surge in a mother's breast, the system having a breast pump with a breast shield for expressing milk from the breast, at least one collecting container, for receiving the milk expressed, and a unit by means of which a quantity of milk received in the at least one collecting container is determined as a function of time.

50

13. The process as claimed in claim 10, wherein, in order to express the milk, use is made of a breast pump with a breast shield, and wherein the milk expressed is directed from the breast shield into the at least one collecting container via a connecting tube.

55

2. The system as claimed in claim 1, wherein the unit has a measuring means, for measuring the quantity of milk located in the at least one collecting container, and an evaluating means by means of which the

14. The process as claimed in claim 10, wherein the milk is collected in several collecting containers, wherein the collecting containers are filled one after the other dependent on a predetermined event.

quantity of milk measured is evaluated as a function of time.

3. The system as claimed in claim 2, wherein the measuring means is a balance.
 4. The system as claimed in claim 3, wherein the balance is an electromechanical balance with a bearing surface for the at least one collecting container.
 5. The system as claimed in claim 2, wherein the evaluating means is a computing system, in particular a computer.
 6. The system as claimed in claim 1, wherein the at least one collecting container is connected to the breast shield via a connecting tube.
 7. The system as claimed in claim 1, wherein the system comprises several collecting containers being connected with said unit for determining the quantity of milk.
 8. The system as claimed in claim 8 and claim 3, wherein said collecting containers are arranged system on said balance.
 9. The system as claimed in claim 7 and claim 6, wherein the system comprises moving means for moving said connecting tube from one of said collecting containers to another of said collecting containers.
 10. A process for detecting a milk surge in a mother's breast, milk being expressed from the breast into at least one collecting container, and the quantity of milk expressed being determined as a function of time.
 11. The process as claimed in claim 10, wherein the weight of the quantity of milk expressed is determined as a function of time.
 12. The process as claimed in claim 10, wherein the change in weight of the quantity of milk expressed is determined as a function of time.
 13. The process as claimed in claim 10, wherein, in order to express the milk, use is made of a breast pump with a breast shield, and wherein the milk expressed is directed from the breast shield into the at least one collecting container via a connecting tube.
 14. The process as claimed in claim 10, wherein the milk is collected in several collecting containers, wherein the collecting containers are filled one after the other dependent on a predetermined event.

15. The process as claimed in claim 14, wherein the predetermined event is the arrival of a set time point.

16. Use of a breast pump for detecting a milk surge in a mother's breast, milk being expressed from the breast into at least one collecting container by means of the breast pump, and the quantity of milk expressed being determined as a function of time.

5

10

15

20

25

30

35

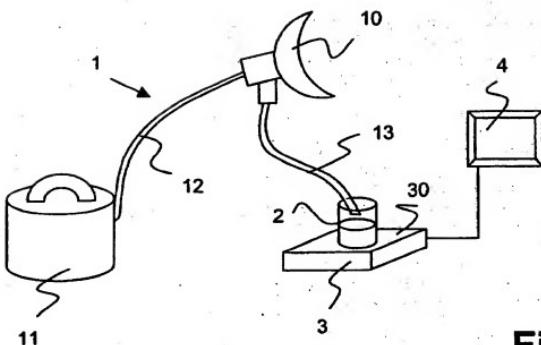
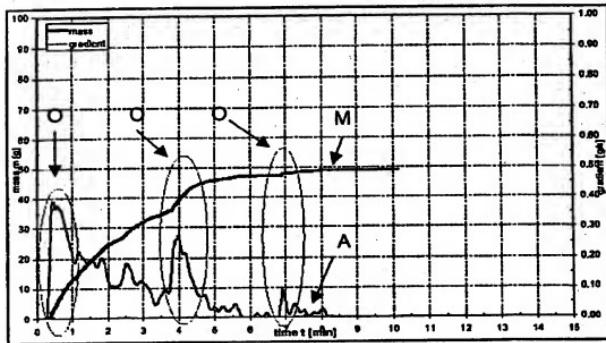
40

45

50

55

5

**Fig. 1****Fig. 2**

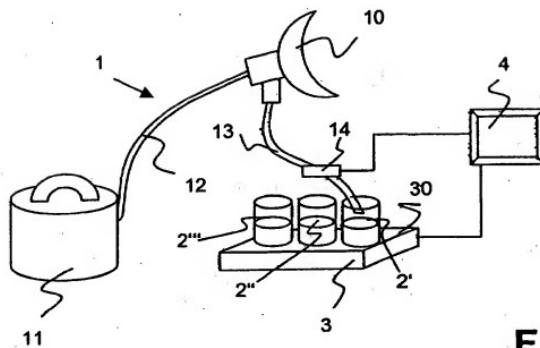


Fig. 3

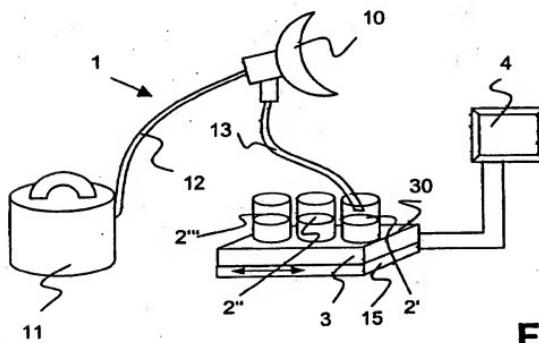


Fig. 4



European Patent
Office

EUROPEAN SEARCH REPORT

Application Number
FP 03 40 5885

DOCUMENTS CONSIDERED TO BE RELEVANT			Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int.Cl.)		
Category	Citation of document with indication, where appropriate, of relevant passages					
X	HARTMANN PETER AND CREGAN MARK: "Lactogenesis and the effects of insulin-dependent diabetes mellitus and prematurity" 2 April 2001 (2001-04-02) , AMERICAN SOCIETY FOR NUTRITIONAL SCIENCES XP002270836 * page 3017S, right-hand column, line 21 - line 36 *		1-6, 10-13,16	A61M1/06 A61B5/00		
Y			14,15			
X	EP 0 116 186 A (AMEDA AG) 22 August 1984 (1984-08-22) * page 14, line 18 - line 20 * * page 16, line 10 - line 13 * * figure 1 *		1,6			
Y			7-9			
P,X	WO 03/028616 A (BARNES GRETCHEN K ;JORDAN ALAN E (US); MANN THEO (US); PURONYX INC) 10 April 2003 (2003-04-10) * page 5, line 31 - line 35 * * page 6, line 9 - line 10 *		1,6	TECHNICAL FIELDS SEARCHED (Int.Cl.)		
D,A	US 5 827 191 A (ROSENFELD HAIM) 27 October 1998 (1998-10-27) * column 2, line 51 - line 55 *		1,10,16	A61M A61B G01N		
D,A	WO 01/47577 A (EIXLER JURGEN ;GRETER ANDY (CH); LARSSON MICHAEL (CH); DETTLING MI) 5 July 2001 (2001-07-05) * page 3, line 13 - line 18 *		1,10,16			
		-/-				
The present search report has been drawn up for all claims						
Place of search	Date of completion of the search		Examiner			
THE HAGUE	23 April 2004		Lakk, A			
CATEGORY OF CITED DOCUMENTS						
X : particularly relevant if taken alone	T : theory or principle underlying the invention					
V : particularly relevant if combined with another document of the same category	E : earlier patent document, but published on, or after the filing date					
A : document cited in the background	D : document cited in the application					
O : non-written disclosure	L : document cited for other reasons					
P : Intermediate document	S : member of the same patent family, corresponding document					



European Patent
Office

EUROPEAN SEARCH REPORT

Application Number
EP 03 40 5885

DOCUMENTS CONSIDERED TO BE RELEVANT					
Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int.Cl.)		
Y	DALY S E J ET AL: "Degree of breast emptying explains change in the fat content, but not fatty acid composition, of human milk" EXPERIMENTAL PHYSIOLOGY, XP008030117 lines 10-12 of the abstract * page 7 * * page 742, paragraph 4 *	7-9,14, 15			
A	CA 2 340 851 A (COMPAC INT INC) 14 September 2001 (2001-09-14) * abstract * & US 6 576 278 A (SPREHE GREGORY S) 10 June 2003 (2003-06-10) * column 1, line 11 - line 15 * * column 1, line 20 - line 21 * * column 6, line 16 - line 20 *	7,14,15			
A	WO 01/74149 A (MELLBERG STEN ;DELAVAL HOLDING AB (SE); GUDMUNDSSON MATS (SE)) 11 October 2001 (2001-10-11) * abstract; figure 1 *	7,9,14, 15	<table border="1"> <tr> <td>TECHNICAL FIELDS SEARCHED (Int.Cl.)</td> </tr> <tr> <td></td> </tr> </table>	TECHNICAL FIELDS SEARCHED (Int.Cl.)	
TECHNICAL FIELDS SEARCHED (Int.Cl.)					
The present search report has been drawn up for all claims					
Place of search	Date of completion of the search	Examiner			
THE HAGUE	23 April 2004	Lakkis, A			
CATEGORY OF CITED DOCUMENTS					
X : particularly relevant if taken alone	T : theory or principle underlying the invention				
Y : particularly relevant if combined with another document of the same category	E : earliest prior document, but published on, or after the filing date				
A : technological background	O : document cited in the application				
G : general document	L : document cited for other reasons				
P : intermediate document	S : member of the same patent family, corresponding document				



European Patent
Office

Application Number

CLAIMS INCURRING FEES

The present European patent application comprised at the time of filing more than ten claims.

- Only part of the claims have been paid within the prescribed time limit. The present European search report has been drawn up for the first ten claims and for those claims for which claims fees have been paid, namely claim(s):

No claims fees have been paid within the prescribed time limit. The present European search report has been drawn up for the first ten claims.

LACK OF UNITY OF INVENTION

The Search Division considers that the present European patent application does not comply with the requirements of unity of invention and relates to several inventions or groups of inventions, namely:

see sheet B

- All further search fees have been paid within the fixed time limit. The present European search report has been drawn up for all claims.

As all searchable claims could be searched without effort justifying an additional fee, the Search Division did not invite payment of any additional fee.

Only part of the further search fees have been paid within the fixed time limit. The present European search report has been drawn up for those parts of the European patent application which relate to the inventions in respect of which search fees have been paid, namely claims:

None of the further search fees have been paid within the fixed time limit. The present European search report has been drawn up for those parts of the European patent application which relate to the invention first mentioned in the claims, namely claims:



The Search Division considers that the present European patent application does not comply with the requirements of unity of invention and relates to several inventions or groups of inventions, namely:

1. Claims: 1-6, 10-13, 16

A system for detecting milk surge as in claim 1, having specific measuring or evaluating means; A process for detecting a milk surge as in claim 10, wherein the weight of the quantity of milk is determined; Use of a breast pump for detecting a milk surge

Problem solved: provide alternative ways of measuring or evaluating the quantity of milk as a function of time (see description, page 3, lines 27-34)

2. Claims: 7-9 (dependent on 1), 14-15 (dependent on 10)

A system for detecting milk surge as in claim 1, comprising several collecting containers; A process for detecting a milk surge as in claim 10, wherein the milk is collected in several collecting containers.

Problem solved: to split the milk collection in order to obtain samples that can be individually analyzed or used, e.g. to track or use the differences in fat content (see description, page 4, lines 16-19, page 7, line 27-page 8, line 2)

ANNEX TO THE EUROPEAN SEARCH REPORT
ON EUROPEAN PATENT APPLICATION NO.

EP 03 40 5885

This annex lists the patent family members relating to the patent documents cited in the above-mentioned European search report.
 The members are as contained in the European Patent Office EPO file on
 The European Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

23-04-2004

Patent document cited in search report		Publication date		Patent family member(s)		Publication date
EP 0116186	A	22-08-1984	AT CA DE EP US	20825 T 1218276 A1 3364783 D1 0116186 A1 4573969 A	15-08-1986 24-02-1987 28-08-1986 22-08-1984 04-03-1986	
WO 03028616	A	10-04-2003	WO	03028616 A2	10-04-2003	
US 5827191	A	27-10-1998	NONE			
WO 0147577	A	05-07-2001	US US US AU CA EP JP NO WO US US	6676631 B1 6547756 B1 6699213 B1 4904001 A 2393832 A1 1263487 A2 2003518412 T 20022743 A 0147577 A2 2003069536 A1 2004024351 A1	13-01-2004 15-04-2003 02-03-2004 09-07-2001 05-07-2001 11-12-2002 10-06-2003 07-08-2002 05-07-2001 10-04-2003 05-02-2004	
CA 2340851	A	14-09-2001	US CA US	6576278 B1 2340851 A1 2003118701 A1	10-06-2003 14-09-2001 26-06-2003	
WO 0174149	A	11-10-2001	AU CA EP JP WO US	4495601 A 2404393 A1 1267607 A1 2003529088 T 0174149 A1 2003143749 A1	15-10-2001 11-10-2001 02-01-2003 30-09-2003 11-10-2001 31-07-2003	